REMARKS

This Amendment is submitted in reply to the non-final Office Action mailed on February 9, 2010. The Office Action provided a three-month shortened statutory period in which to respond, ending on May 9, 2010. Accordingly, this amendment is timely submitted. No fees are believed due with this Amendment. The Director is authorized to charge any fees that may be required, or to credit any overpayment to Deposit Account No. 50-4498 in the name of Nestle Nutrition.

Claims 1-47 are currently pending in this application. Claims 1-9, 33, 36, 37 and 41-44 were previously withdrawn from consideration. In the Office Action, Claims 34 and 35 are objected to. Claims 10-32, 34-35, 38-40 and 45-47 are rejected under 35 U.S.C. §102. Applicant does not acquiesce in the correctness of the rejections or objections and reserves the right to present specific arguments regarding any rejected or objected-to claims not specifically addressed. Further, Applicant reserves the right to pursue the full scope of the subject matter of the claims in a subsequent patent application that claims priority to the instant application.

In response, Claims 10, 12-24, 26-32, 38-40 and 45-47 have been amended and Claims 11, 25 and 34-35 have been canceled without prejudice or disclaimer. These amendments do not add new matter. The amendments are supported in the specification at, for example, page 3, lines 20-29; page 5, lines 1-19; page 13, lines 13-17. In view of the amendments and/or for the reasons set forth below, Applicant respectfully submits that the rejections should be reconsidered and withdrawn.

In the Office Action, Claims 34-35 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Specifically, the Patent Office states that since Claim 30 is drawn to a composition, Claims 34-35 do not further limit Claim 30. See, Office Action, page 4, lines 13-20. In response, Applicant has canceled Claims 34-35, which were intended to depend from Claims 33 and 34, respectively. Accordingly, Applicant respectfully requests that the objection to Claims 34-35 be reconsidered and withdrawn.

In the Office Action, Claims 10, 23-24, 27 and 45 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,270,803 to Blatt et al. ("*Blatt*"). Claims 10-12, 22-26, 29-32, 34-35, 38 and 45 are rejected under 35 U.S.C. §102(b) as being anticipated by Kuttan et

al. (*"Kuttan"*). Claims 10-32, 34-35, 38-40 and 45-47 are rejected under 35 U.S.C. §102(b) as being anticipated by WO 98/50054 to Mühlbauer (*"Mühlbauer"*). Applicant respectfully submits that the cited references are deficient with respect to the present claims.

Currently amended independent Claims 10 and 24 recite, in part, nutritional and pharmaceutical compositions, respectively, comprising a γ-glutamyl-peptide selected from the group consisting of γ-glutamyl-alkyl-cysteine sulfoxide, γ-glutamy-alkenyl-cysteine sulfoxide, and combinations thereof, a carrier, and a fat source. The amendments do not add new matter and are supported in the specification at, for example, page 3, lines 20-29; page 5, lines 1-19; page 13, lines 13-17. Currently amended independent Claim 29 recites, in part, a method of obtaining a γ-L-glutamyl-trans-S-1-propenyl-L-cysteine sulfoxide by fractionation of an hydrophilic, ethanolic extract of Allium, the method comprising the steps of obtaining an hydrophilic, ethanolic extract of Allium cepa, separating saccharides from fraction A, further separating saccharides from fraction A1, and further fractionation by semi-preparative reversed-phase HPLC (SP-RP-HPLC) using a solvent. The amendments do not add new matter and are supported in the specification at, for example, page 3, lines 20-29; page 5, lines 1-19; page 13, lines 13-17.

Applicant has surprisingly found that the active constituent of allium responsible for the bone resorption inhibiting effect may be found in a hydrophilic, ethanolic extract of allium such as allium cepa. The active constituent having a potent inhibitory effect on bone resorption was identified as a γ-glutamyl-peptide, for example a γ-glutamyl-alkyl-cysteine sulfoxide or γ-glutamyl-alkenyl-cysteine sulfoxide, or a γ-L-glutamyl-trans-S-1-propenyl-L-cysteine sulfoxide. See, specification, page 7, lines 32-37. In contrast, *Blatt, Kuttan* and *Mühlbauer* fail to disclose every element of the present claims.

For example, *Blatt*, *Kuttan* and *Mühlbauer* fail to disclose or suggest nutritional and pharmaceutical compositions, respectively, comprising a γ-glutamyl-peptide selected from the group consisting of γ-glutamyl-alkyl-cysteine sulfoxide, γ-glutamy-alkenyl-cysteine sulfoxide, and combinations thereof, a carrier, and a fat source as required, in part, by currently amended independent Claims 10 and 24. Instead, *Blatt* is entirely directed to orally-administered formulations including powdered and/or granulated garlic. See, *Blatt*, Abstract; Background. At no place in the disclosure does *Blatt* disclose or suggest a γ-glutamyl-peptide selected from the

group consisting of γ-glutamyl-alkyl-cysteine sulfoxide, γ-glutamy-alkenyl-cysteine sulfoxide, and combinations thereof as required, in part, by independent Claims 10 and 24.

Kuttan is entirely directed to the isolation and characterization of γ-L-glutamyl-S-(trans-1-propenyl)-L-cysteine sulfoxide from sandal (*Santal album L.*). See, *Kuttan*, Abstract. At no place in the disclosure, however, does *Kuttan* disclose or suggest nutritional or pharmaceutical compositions comprising a γ-glutamyl-peptide selected from the group consisting of γ-glutamyl-alkyl-cysteine sulfoxide, γ-glutamy-alkenyl-cysteine sulfoxide, and combinations thereof, a carrier, and a fat source as required, in part, by currently amended independent Claims 10 and 24.

Mühlbauer is entirely directed to plant extracts for the treatment of increase bone resorption. See, *Mühlbauer,* Abstract. The Patent Office asserts that *Mühlbauer* teaches a nutritional composition comprising all of the active components of the instant claims. See, Office Action, page 7, lines 9-10. Applicant respectfully disagrees, however, and submits that the Manual of Patent Examining Procedure clearly states that "[a] genus does not always anticipate a claim to a species within the genus. However, when the species is clearly named, the species claim is anticipated no matter how many other species are additionally named." *Ex parte A,* 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990). Indeed, the disclosure of a large genus rarely anticipates a narrowly claimed species.

For example, in the Court of Customs and Patent Appeals case of *In re Petering,* a test for determining whether a disclosed genus is sufficiently small enough to anticipate a claimed species was established. 301 F.2d 676, (CCPA 1962). The application at issue in *Petering* contained claims to a particular species of compound. The Examiner cited a reference disclosing a chemical genus, which included the claimed species, having a limited number of substituent groups that represented either hydrogen or alkyl radicals, and an R group containing an OH group. The court held that this formula alone could not anticipate the claimed species because there were too many compounds within this disclosed genus - the genus was too large. The reference, however, also disclosed preferred substituent groups, which included about twenty compounds defining a subgenus. The court found that one of ordinary skill in the art would have been informed enough by the reference to "at once envisage" each member of the subgenus, which included the claimed species. *Id.* Accordingly, the genus-species anticipation test states

that a genus anticipates a species if one of ordinary skill in the art is able to "envisage" the claimed species within the disclosed genus. This test was later confirmed by the CCPA in *In re Schauman*, 572 F.2d 312, (CCPA 1978).

Recent Federal Circuit case law has confirmed that the *Petering* and *Schauman* analysis remains the test when considering whether or not a prior art document's disclosure of a genus anticipates a claimed species. See, *Sanofi-Synthelabo v. Apotex, Inc.,* 550 F.3D 1075, 1084 (Fed. Cir. 2008) and *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.,* 471 F.3d 1369, 1376 (Fed. Cir. 2006) (citing *Petering* and *Schauman* and emphasizing that the disclosure of a broad genus can be narrowed to a specific group of compounds if the reference also discloses preferred embodiments or compounds). As such, Applicant submits that, although *Mühlbauer* discloses the genus *allium* and mentions *allium cepa*, *Mühlbauer* fails to anticipate the present claims because the genus *allium cepa* is too large for the skilled artisan to envisage a γ-glutamyl-peptide extracted from *allium cepa*, let alone a specific γ-glutamyl-peptide selected from the group consisting of γ-glutamyl-alkyl-cysteine sulfoxide, γ-glutamy-alkenyl-cysteine sulfoxide, and combinations thereof as required, in part, by currently amended independent Claims 10 and 24.

Further, *Kuttan* and *Mühlbauer* fail to disclose or suggest a method of obtaining a γ-L-glutamyl-trans-S-1-propenyl-L-cysteine sulfoxide by fractionation of an hydrophilic, ethanolic extract of *Allium*, the method comprising the steps of obtaining an hydrophilic, ethanolic extract of *Allium cepa*, separating saccharides from fraction A, further separating saccharides from fraction A1, and further fractionation by semi-preparative reversed-phase HPLC (SP-RP-HPLC) using a solvent as required, in part, by currently amended independent Claim 29. Indeed, neither *Kuttan* nor *Mühlbauer* disclose or suggest methods for obtaining a γ-L-glutamyl-trans-S-1-propenyl-L-cysteine sulfoxide by fractionation of an hydrophilic, ethanolic extract of *Allium*, let alone the specific steps necessary to accomplish the fractionation.

Further, anticipation is a factual determination that "requires the presence in a single prior art disclosure of each and every element of a claimed invention." *Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744, 747 (Fed. Cir. 1987) (emphasis added). Federal Circuit decisions have repeatedly emphasized the notion that anticipation cannot be found where less than all elements of a claimed invention are set forth in a reference. See, *e.g.*, *Transclean Corp. v. Bridgewood Services, Inc.*, 290 F.3d 1364, 1370 (Fed. Cir. 2002). As such, a reference must

clearly disclose each and every limitation of the claimed invention before anticipation may be found. In the instant case, the Patent Office has failed to identify the disclosure of each and every limitation of the claimed invention.

For at least these reasons, Applicant respectfully submits that *Blatt*, *Kuttan* and *Mühlbauer* fail to disclose or suggest each and every element of the present claims.

Accordingly, Applicant respectfully requests that the anticipation rejections of Claims 10-32, 34-35, 38-40 and 45-47 under 35 U.S.C. §102(b) be reconsidered and withdrawn.

For the foregoing reasons, Applicant respectfully requests reconsideration of the above-identified patent application and earnestly request an early allowance of the same. In the event there remains any impediment to allowance of the claims which could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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